

06-21-04

1645  
ELW



IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants: Panaccio, et al.

Serial No. 10/009,919

Filed: 06/14/02

For: LAWSONIA DERIVED GENE AND RELATED HEMOLYSIN  
POLYPEPTIDES, PEPTIDES AND PROTEINS AND THEIR USES

Attorney Docket No: 3153.00184/PC10563A

**RESPONSE**

Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450  
Mail Stop Non-Fee Amendment

Dear Sir:

This Response is being submitted in response to an Office Action dated May 20, 2004.

Restriction to one of the following groups is required under 35 USC § 121:

Group I, claims 1-4, 6-8, 10, 11, 13, 14 and 17-26 drawn to an isolated or recombinant immunogenic polypeptide comprising the Lawsonia hemolysin polypeptide, variant or truncated variant thereof, a vaccine composition comprising SEQ ID NO. 1 or the amino acid sequence encoded by pALK 12;

Group II, claims 28-30, 37-42, 46 and 47 drawn to a vaccine vector, polynucleotide that encodes the immunogenic polypeptide SEQ ID NO. 1 or polynucleotide, SEQ ID NO. 2 or Plasmid pALK 12 or Plasmid pALK 13;

Group III, claims 31-33 drawn to antibody that binds to SEQ ID NO: 1 or the amino acid sequence encoded by pALK 12;

Group IV, claims 27 and 48 drawn to a combination vaccine composition comprising the first component comprising the amino acid sequence set forth in SEQ ID NO: 1 or the amino acid sequence encoded by pALK 12 and a second immunogenic component comprising OmpH, FigE, hemolysin and autolysin;

Group V, claims 34-35 drawn to a method for diagnosing the infection of *L. intracellularis* using an antibody that binds to SEQ ID NO: 1 or the amino acid sequence encoded by pALK 12;

Group VI, claim 36 drawn to a method of identifying a previous infection or current infection *Lawsonia intracellularis* using an immunogenic polypeptide, SEQ ID NO: 1 or the amino acid sequence encoded by pALK 12; and

Group VII claims 43-45 drawn to a method for identifying *Lawsonia intracellularis* in a sample using DNA polynucleotide that encodes the immunogenic polypeptide SEQ ID NO: 1 or polynucleotide, SEQ ID No: 2 or Plasmid pALK 12 or Plasmid pALK 13.

Applicants provisionally elect with traverse, Group I, claims 1-4, 6-8, 10, 11, 13, 14, and 17-26. Additionally, Applicants provisionally elect, with traverse, SEQ ID NO. 1 for prosecution purposes

Applicants hereby conditionally withdraw claims 5, 9, 12, 15, 16, and 27-48 from prosecution, without prejudice, and request reconsideration of the restriction requirement.

Applicants traverse the restriction requirement based on the following

grounds. It is respectfully submitted that the restriction requirement practice was established to promote efficiency of prosecution in the United States Patent Office. All of the Groups of claims relate to therapeutic compositions for the treatment and/or prophylaxis of intestinal disease in animals and birds caused or exacerbated by *Lawsonia Intracellularis* or other similar related organisms. More specifically, the present invention provides a novel gene derived from *Lawsonia Intracellularis*, which encodes an immunogenic hemolysin peptide, polypeptide, or protein. This hemolysin polypeptide is useful as an antigen in vaccine preparation for conferring humoral immunity against *Lawsonia Intracellularis* and other related pathogens in animal hosts. Furthermore, the present invention provides for various related methods associated with the polypeptide and its use thereof. It is a well-established and accepted practice in the United States Patent Office to claim a polypeptide, a related vaccine vector, including a polynucleotide that encodes the polypeptide, vaccine compositions thereof, antibodies that bind to the polypeptide, and various methods related to the polypeptide or antibody thereof. Accordingly, Applicants believe that it is entirely reasonable and would not present an undue burden on the Examiner, for the claims of the group to be prosecuted together in the instant application. It is respectfully submitted that the examination of all of these groups of claims in a single application would be efficient and thereby promotes the grounds for the establishment of the restriction requirement practice. Hence, it is respectfully

USSN Number: 10/009,919

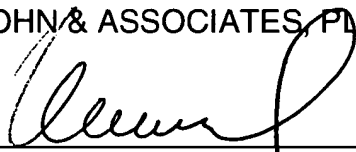
requested that the restriction should not be required and that Applicants have traversed the restriction requirement. However, as stated above, Applicants have provisionally elected the claims of Group I and SEQ ID NO: 1. Moreover, Applicants have provisionally withdrawn claims, 5, 9, 12, 15, 16, and 27-48, without prejudice, pending reconsideration of the restriction requirement.

The application is now in condition for allowance, which allowance is respectfully solicited.

The Commissioner is authorized to charge any fee or credit any overpayment in connection with this communication to our Deposit Account No. 11-1449.

Respectfully submitted,

KOHN & ASSOCIATES, PLLC



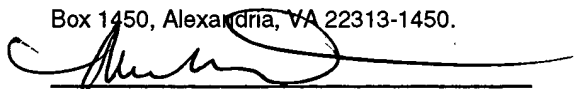
Kenneth I. Kohn, Reg. No. 30,955  
30500 Northwestern Highway  
Suite 410  
Farmington Hills, Michigan 48334  
(248) 539-5050

Dated: June 17, 2004

**CERTIFICATE OF MAILING BY "EXPRESS MAIL"**

Express Mail Mailing Label No: EV 442 292 946 US  
Date of Deposit: June 17, 2004

I hereby certify that this paper or fee is being deposited with the United States Postal Service "Express Mail Post Office To Addressee" service under 37 CFR 1.10 on the date indicated above and is addressed to: Mail Stop: Non-Fee Amendment Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.



Marie M. DeWitt